MINISTRY OF HEALTH MALAYSIA

MALAYSIAN NATIONAL MEDICINES POLICY

2nd Edition, 2012

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- Malaysian Association of Pharmaceutical Suppliers (MAPS)
- Association of Private Hospitals Malaysia (APHM)
- Consumer Association of Penang (CAP)
- Federation of Malaysian Consumers Associations (FOMCA)
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- Malaysia Competition Commission (MyCC)
- Intellectual Property Corporation of Malaysia (MyIPO)
- Forest Research Institute Malaysia (FRIM)
- Malaysia Biotechnology Corporation Sdn. Bhd.
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- Direct Selling Association of Malaysia (DSAM)
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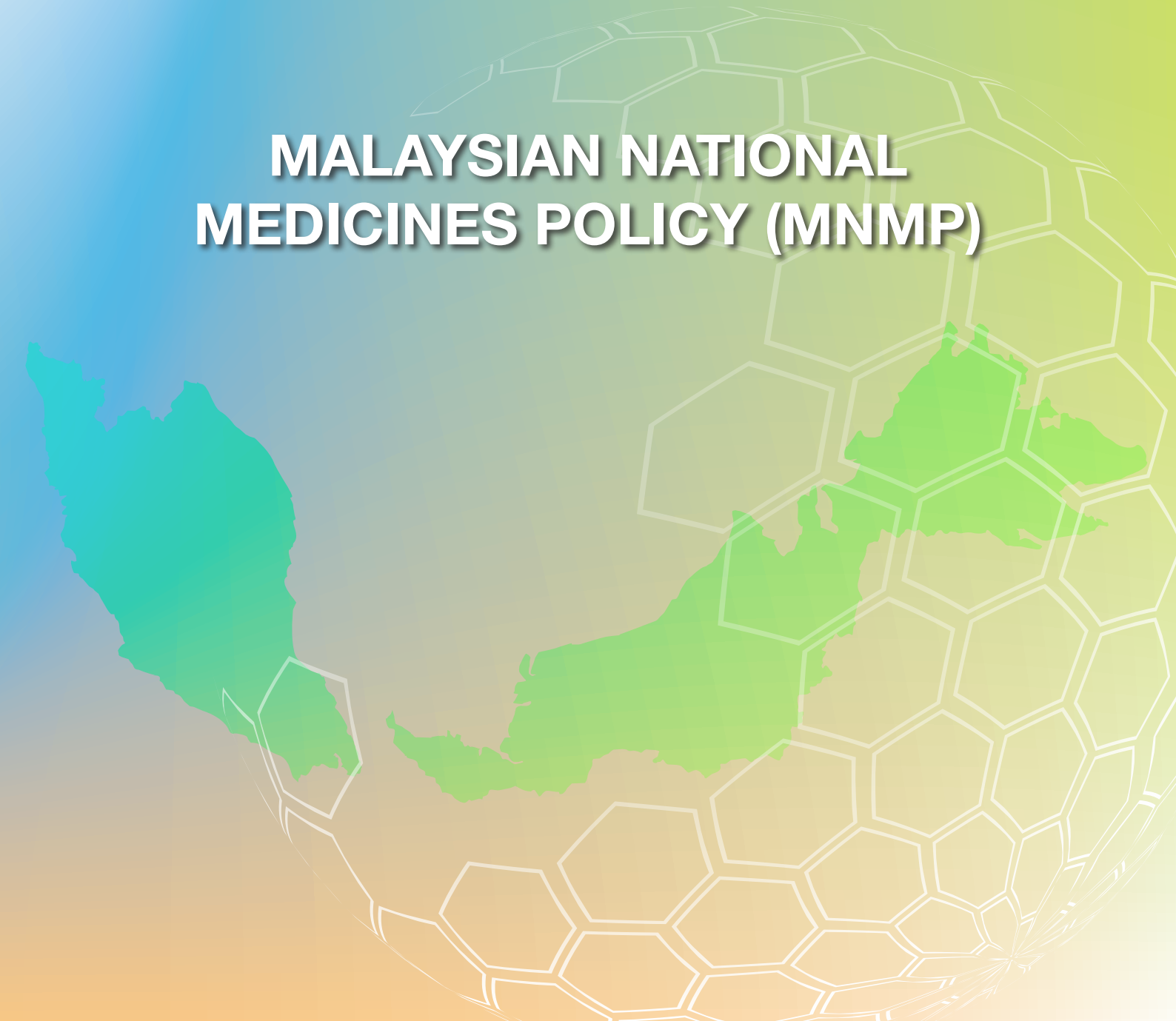
MALAYSIAN NATIONAL MEDICINES POLICY (MNMP)



MALAYSIAN NATIONAL MEDICINES POLICY (MNMP)

PREAMBLE

The Malaysian National Medicines Policy (MNMP), which was endorsed by the Malaysian Cabinet in October 2006, is the way forward for the nation to ensure good medicines management for better health outcomes of all Malaysians. The mid-term review of the policy was done in July 2009 followed by the full-term review in October 2012.

This second edition of the MNMP is a documented review of the policy after five years of its implementation. A review and revision of the original policy is essential to address important issues and identify areas for improvement, incorporating changes where necessary to meet the current and future health care needs of the nation.

INTRODUCTION

The objective of the National Medicines Policy remains the same that is to promote equitable access and rational use of safe, effective and affordable essential medicines of good quality to improve health outcomes of the people.

The five years of policy implementation has shown tremendous positive outcomes and transformation such as establishing a comprehensive regulation system, strengthening of the laws and regulations, creating a robust pharmaceutical industry as well as developing an extensive pharmaceutical distribution network. However, certain areas still require further improvement and strengthening, embracing new ideas while still maintaining the existing policy objective.

The introduction of new policy statements and strategies are vital for the pharmaceutical and health sectors to move forward and to provide for the present needs of the nation, as well as to improve and support existing government policies in line with current global developments.

The four core components and four supporting components of the original policy have been reorganised. *The Quality, Safety and Efficacy* as well as *Quality Use of Medicines* components are maintained. The *Medicines Availability* and *Medicines Affordability* components are combined into one component entitled *Access to Medicines* to prevent overlapping of strategies and issues. *Human Resources Development, Research and Development and Technical Cooperation* components are incorporated into one component named *Partnership and Collaboration for the Healthcare Industry*. A new component concerning governance in medicines is introduced into this revised policy.

These modifications resulted in five final components that are:

i. Governance in Medicines
ii. Quality, Safety and Efficacy of Medicines
iii. Access to Medicines
iv. Quality Use of Medicines
v. Partnership and Collaboration for the Healthcare Industry

1
GOVERNANCE IN MEDICINES

1. GOVERNANCE IN MEDICINES

POLICY

Good governance, practices, conduct and professionalism shall be emphasised within the healthcare industry towards achieving optimal health outcomes.

1.1 AIM

To have appropriate governance that ensures the provision of safe, effective and affordable medicines within the best practice environment.

To ensure all stakeholders are responsible for conducting themselves in an ethical and professional manner.

To ensure regulations facilitate and support the provision of safe, effective and affordable medicines.

1.2 STRATEGY

Health professional bodies and relevant stakeholders shall have codes of conduct and be responsible for ensuring compliance by its members with the code.

Stakeholders shall perform in accordance with the standards of practice developed by appropriate authorities or relevant professional bodies. Compliance with the standards shall be supported by legislation where appropriate.

Relevant legislation/regulations shall be developed and reviewed regularly to ensure an efficient supply chain network and integrated medicines management to safeguard the public.

2
QUALITY, SAFETY AND EFFICACY OF MEDICINES

2. QUALITY, SAFETY AND EFFICACY OF MEDICINES

POLICY

Only safe, efficacious and quality medicines that meet approved standards and specifications shall be registered and made available for sale and use by all consumers in Malaysia.

2.1 AIM

To ensure that medicines marketed for consumers are safe, effective and of quality, and to promote quality use of medicines to meet the health needs of the nation.

2.2 STRATEGY

The aim shall be achieved by strengthening the medicines regulatory system through a comprehensive medicines legislation framework, enhanced measures for pharmaceutical quality assurance and effective post-marketing surveillance with positive cooperation and collaboration between the regulators and the relevant stakeholders.

2.2.1 LEGISLATION AND REGULATIONS

Effective and comprehensive medicines legislation shall be instituted for the implementation of the National Medicines Policy. Medicines legislation and regulations shall be managed through judicious and transparent criteria and processes.

Regulations shall be strengthened to ensure appropriate practices are followed in the development, production, importation, supply, marketing, sale and management (including prescribing, dispensing, administration and disposal) of medicines.

The level of regulation shall be consistent with potential benefits and risks to the community.

2.2.1.1 National Pharmaceutical Control Bureau (NPCB)

The National Pharmaceutical Control Bureau (NPCB) shall be responsible for the pharmaceutical regulatory control in Malaysia for:

- Licensing of manufacturers, importers and wholesalers
- Registration of medicines
- Quality control of medicines
- Good Laboratory Practice (GLP) compliance
- Post-marketing surveillance activities
- Control of medicines used in clinical trials

The NPCB shall collaborate with the industry and other stakeholders in order to strengthen the regulatory framework and community engagement, enhance communication and encourage effective use of medicines by the consumers.

The NPCB shall play a prominent role in facilitating regional and international harmonisation of technical requirements for the registration of medicines.

2.2.1.2 Regulating Premises that Supply Medicines

Only licensed manufacturers, importers, wholesalers and authorised retailers shall handle registered medicines.

The sale, supply and dispensing of medicines shall be carried out at premises regulated according to the appropriate legislations.

2.2.1.3 Effective Enforcement

Drug legislation and regulations shall be supported by adequate and effective enforcement to ensure that all activities in the manufacturing and supply of medicines comply with existing legislations, regulations, guidelines and directives.

Premises that manufacture, import, supply or dispense medicines shall be inspected regularly to ensure compliance to existing regulatory requirements.

2.2.1.4 Medicines Advertisement and Promotion

All relevant stakeholders shall comply with existing legislations, guidelines and relevant codes of ethics for advertising and promotion.

2.2.1.5 Counterfeit Medicines

Appropriate legal and technical framework for concerted efforts in the enforcement of laws and regulations by the Ministry of Health and other relevant authorities relating to market surveillance shall be further enhanced to overcome the problem of counterfeit medicines.

Suitable security measures for authentication, traceability of counterfeit medicines and public education shall be implemented and continuously enhanced.

2.2.2 PHARMACEUTICAL QUALITY ASSURANCE

2.2.2.1 Post-Marketing Surveillance

There shall be continuous monitoring on products available in the market in order to ensure conformity of the products to the current standards and requirements. Necessary punitive action shall be taken on non-conforming products.

2.2.2.2 Management of Complaints about Medicines

All complaints pertaining to medicines shall be investigated and appropriate action shall be taken in a timely manner.

3
ACCESS TO MEDICINES

3. ACCESS TO MEDICINES

POLICY

An efficient and integrated medicines management and supply network shall be maintained. The pharmaceutical industry shall be organised and regulated to create incentives and foster competition in medicine prices. Appropriate financing mechanisms shall be developed to ensure essential medicines needed for quality healthcare are affordable.

3.1 AIM

To ensure adequate, continuous and equitable access to quality, safe, effective and affordable medicines towards achieving optimal health outcomes.

3.2 STRATEGY

The aim shall be achieved by ensuring the availability and affordability of medicines through:

- A fair and transparent medicines selection mechanism in accordance with the country's health needs by emphasising clinical effectiveness and cost-effectiveness of treatments
- An efficient and effective procurement mechanism and supply chain network of quality medicines
- An efficient financing management mechanism for optimising health outcomes to ensure value for money

3.2.1 AVAILABILITY OF MEDICINES

Availability of medicines shall be achieved through the appropriate selection of medicines, improvement in the management of medicines procurement and the supply chain network, and through optimal utilisation of available financial resources to ensure sustainability.

3.2.1.1 Selection of Medicines

Selection of medicines shall be transparent and based on the principles of quality, safety, efficacy, clinical effectiveness and cost-effectiveness of the treatment based on standard clinical practice.

3.2.1.1.1 National Medicines Formulary

A National Medicines Formulary that encompasses the National Essential Medicines List (NEML) shall be developed by the National Drug and Therapeutic Committee, which shall serve as a standard reference for the country.

The National Medicines Formulary serves as guide for the purpose of prescribing and thus, providing healthcare professional with practical and authoritative information on the selection and clinical use of medicines in a clear, concise and accessible manner.

3.2.1.1.2 National Essential Medicines List (NEML)

The NEML shall be revised and updated regularly to serve as the national reference for domestic medicines industry for the purpose of production, procurement, distribution, utilisation and research as well as to the healthcare academia in their teaching curriculum.

3.2.1.1.3 Drug and Therapeutic Committee

The National Drug and Therapeutic Committee shall be represented by all relevant stakeholders under the auspices of the Ministry of Health.

The drug and therapeutic committees of institutions and local health facilities shall be responsible in the selection of medicines, ensuring availability and affordability for use by their healthcare providers. They shall develop and coordinate their in-house policies related to medicines by referring to and adopting the National Medicines Formulary and standard clinical practice.

The drug and therapeutic committees can recommend and decide on the use of medicines not listed in the National Medicines Formulary depending on specific clinical needs and requirements based on their resource allocations. However, the national drug and therapeutic committee shall monitor the utilisation of these drugs.

All drugs and therapeutic committees shall be established according to the guidelines developed by Ministry of Health.

3.2.1.1.4 Traditional and Complementary Medicines Formulary

A formulary of traditional and complementary medicines shall be developed by an expert advisory committee under the auspices of the Ministry of Health. This formulary shall serve as a guide for the use of registered traditional and complementary medicines by healthcare providers.

3.2.1.1.5 Life-saving Medicines and Orphan Medicines

There shall be appropriate procedures to enhance accessibility of life-saving products and orphan medicines without compromising safety, quality and efficacy.

3.2.1.1.6 Halal Medicines

There shall be strategic partnerships with the relevant authorities to make certified halal medicines available in Malaysia.

3.2.1.2 Supply of Medicines

There shall be an equitable, adequate and timely supply of safe, effective and quality medicines. This shall be achieved by implementing:

- Effective management of the medicines supply chain network based on a comprehensive quality system
- Efficient and coordinated medicines supply chain network in compliance with Good Distribution Practice (GDP)
- Effective and integrated Information and Communication Technology (ICT) to support the supply chain network

3.2.1.2.1 Procurement

An efficient, effective and transparent procurement system shall be strengthened to ensure adequate and timely availability of medicines.

3.2.1.2.2 Distribution and Storage of Medicines

An efficient and economical distribution network shall be strengthened to ensure timely distribution of adequate quantities of quality medicines to end users.

Storage, inventory control and quality assurance in facilities and throughout the supply chain network shall comply with GDP requirements to ensure quality and security of medicines.

The ICT network for logistics, inventory and financial transactions shall be established and integrated in all healthcare facilities.

3.2.1.2.3 Disposal of Medicines

Disposal of medicines shall be done in accordance with existing regulations and guidelines.

3.2.1.2.4 Medicines Supply in Emergency Situations and Medicines Donations

All organisations shall collaborate and be coordinated to manage national emergency situations to ensure timely supplies of these medicines without compromising safety, quality and efficacy.

Management of medicines in emergency situations or as donations shall be based on expressed needs as recommended by the WHO Guidelines for medicine donations from donors to recipients.

3.2.2 AFFORDABILITY OF MEDICINES

Medicines needed for quality health care shall be affordable to all. Cost shall not become a barrier to ensure that medicines are available to the population. Efforts shall be taken to promote healthy competition towards fair, transparent and sustainable cost-effective treatments.

3.2.2.1 National Pricing Reference for Medicines

The National Pricing Reference for Medicines in the National Medicines Formulary shall be developed by a committee comprising relevant stakeholders. It shall encompass the principles of equity, affordability and transparency.

3.2.2.1.1 Transparency on Price Information

All stakeholders shall collaborate to strive for transparency on medicine prices in Malaysia through:

- Development of a medicines price database
- The availability of Recommended Retail Price (RRP) for public access
- Compulsory itemised billing indicating the price of each item bought or supplied at all dispensing channels
- The availability of patent information data

3.2.2.1.2 Monitoring of Price Information

The local and international prices of medicines shall be monitored regularly to detect price changes and other influences in the market so that action can be taken to contain any undue price increase.

3.2.2.1.3 Tariffs and Duties

Supply of medicines shall continue to be exempted from tariffs and duties.

3.2.2.2 Financing for Medicines

A reliable, affordable and sustainable financing mechanism shall be established to achieve universal access to medicines. There shall be planning, budgeting and securing of sufficient funding for the supply of medicines with emphasis on cost-containment measures.

The financing mechanism shall ensure that the poor and underprivileged are not deprived of access to essential medicines.

3.2.2.3 Generic Medicines Policy

The Generic Medicines Policy shall be implemented to foster healthy competition in medicines pricing. This shall be used to guide the use and procurement of medicines as follows:

- Prescribing in generic International Non-proprietary Name (INN) shall be practised at all channels
- Procurement of all medicines by generic INN shall be promoted
- In selection for procurement, priority shall be given to domestically manufactured medicines
- All dispensed medicines shall be labelled prominently with the generic INN of the medicine with or without the brand name
- A list of interchangeable and non-interchangeable medicines shall be made available
- Generic substitution shall be permitted and legislated for all interchangeable medicines
- Appropriate incentives to promote the use of generic medicines and their production in the country shall be introduced

4
QUALITY USE OF MEDICINES

4. QUALITY USE OF MEDICINES

POLICY

Quality use of medicines is the responsibility of all stakeholders. Activities by relevant stakeholders in support of informed and appropriate use of medicines shall be encouraged and promoted.

4.1 AIM

To ensure medicines are used judiciously, appropriately, safely and cost-effectively towards promoting better health outcomes.

4.2 STRATEGY

The aim shall be achieved through:

- Development and implementation of models of best practice
- Education and training
- Provision of timely and accurate information on medicines
- Strengthening seamless care between public and private health care providers
- Research and development in quality use of medicines
- Engagement of payers involved in reimbursements for medicines use

4.2.1 DEVELOPMENT AND IMPLEMENTATION OF MODELS OF BEST PRACTICE

Standards of best practice shall be applied and monitored to ensure the provision of safe and quality use of medicines at all levels of healthcare.

Prescribing and dispensing of medicines shall be in accordance with Clinical Practice Guidelines (CPGs), Standard Treatment Guidelines (STGs), Good Dispensing Practice and other relevant guidelines, which take into account principles of quality, safety and cost-effectiveness. These guidelines shall be made available and readily accessible to all healthcare providers and stakeholders. Periodic reviewing and updating of these guidelines shall be done in line with international practice and local requirements.

Regular audits, monitoring and surveillance activities shall be undertaken to ensure compliance with the relevant guidelines.

Existing mechanisms for the development and updating of guidance documents, clinical guidelines, conducting health technology assessments and pharmacoeconomic evaluations for the nation shall be strengthened.

4.2.2 EDUCATION AND TRAINING

4.2.2.1 Healthcare Providers

Curricula for the education and training of all healthcare providers involved in medication management shall include principles of safe, appropriate and quality use of medicines.

4.2.2.2 Consumers

Health literacy and empowerment of consumers to better manage their medicines shall be improved.

Areas of focus include:

- Medication adherence
- Development of a discerning attitude towards sources of medicines information
- Encouragement of informed decision-making on responsible self-medication
- Proper storage and safe disposal of medicines
- Confidence to interact with healthcare providers

The provision of consumer education and training is a shared responsibility between the Ministry of Health and other stakeholders.

4.2.2.3 Pharmaceutical Industry

All personnel involved in medicines sales and promotion shall have adequate training in quality use of medicines and be governed by a code of ethics.

4.2.2.4 Media

All media personnel involved in health reporting shall have appropriate training and education on quality use of medicines.

4.2.3 PROVISION OF TIMELY AND ACCURATE INFORMATION ON MEDICINES

4.2.3.1 Healthcare Providers

Independent, high quality, evidence-based information shall be made readily available to healthcare providers via continuing education programmes, unbiased promotion of medicines and linkages to the National Drug Information Centre and other relevant health portals.

4.2.3.2 Consumers

Consumers shall have access to accurate information on medicines from a variety of sources including healthcare providers and health portals.

4.2.3.3 Pharmaceutical Industry

The pharmaceutical industry shall provide balanced and responsible information in the promotion of medicines to healthcare providers and consumers.

They shall ensure that the packaging, product information leaflets and medicine labelling are accurate, adequate and unbiased.

Ethical advertising and promotions of medicines shall facilitate quality use of medicines.

4.2.3.4 Media

The media shall practise accurate and responsible reporting on medicines.

Relevant agencies and stakeholders shall provide timely responses in cases of misinformation.

4.2.4 STRENGTHENING SEAMLESS CARE BETWEEN HEALTHCARE PROVIDERS

Comprehensive Information and Communication Technology (ICT) shall be developed as an enabler to facilitate seamless care.

Access to adequate patient medical records, e.g., medication history, drug allergy, etc., shall be provided to facilitate continuity of care without compromising patient's confidentiality.

Smart partnerships and collaborations shall be optimised for best patient care.

4.2.5 RESEARCH AND DEVELOPMENT IN QUALITY USE OF MEDICINES

Studies shall be conducted to evaluate the effectiveness of quality use of medicines programmes and to identify areas that need improvements.

4.2.6 ENGAGEMENT OF PAYERS INVOLVED IN REIMBURSEMENTS FOR MEDICINES USE

Payers shall be responsible to support and engage in activities of quality use of medicines for the aim of optimising health outcomes.

5
PARTNERSHIP AND COLLABORATION FOR THE HEALTHCARE INDUSTRY

5. PARTNERSHIP AND COLLABORATION FOR THE HEALTHCARE INDUSTRY

POLICY

Partnership and collaboration in the implementation and strengthening of relevant areas in the healthcare industry shall be established among various stakeholders at the national, regional and international levels.

5.1 AIM

To ensure that partnership and collaboration of all relevant stakeholders in the healthcare industry conforms to the best practices and standards pertaining to medicines at the national, regional and international levels.

5.2 STRATEGY

The aim shall be achieved by:

- Early and continuous engagement of all relevant stakeholders
- Ensuring sustainability of qualified, competent and effective human resource based on needs through:
  - Training and development
  - Development and advancement of professional career pathway
- Sharing of information, expertise, skills and facilities
- Developing a viable domestic and maintaining a responsible medicines industry

5.2.1 HUMAN RESOURCE DEVELOPMENT

Quality assurance mechanism shall be developed, reviewed and enforced on all training providers to comply with policies and standards.

Training providers shall be transformed to produce quality healthcare professionals who are able to function effectively and efficiently in meeting the country's healthcare needs.

Training programmes for healthcare providers and relevant stakeholders shall be in place to include relevant concepts that ensure quality use of medicines.

Career pathways for healthcare providers shall be identified and implemented for future career development.

5.2.2 RESEARCH AND DEVELOPMENT

Coordination between research institutions and the relevant ministries shall be strengthened.

Research in priority areas shall be identified and reviewed regularly for implementation.

Innovative research and development shall strongly be encouraged through the provision of appropriate incentives.

Transfer, acquisition and development of technology between foreign and local companies shall also be strongly encouraged.

5.2.3 TECHNICAL COLLABORATION AND PARTNERSHIP

Technical collaboration and partnership shall include all areas in regulatory practices, training and human resource development, medicines accessibility, quality use, and research and development.

Effective networking shall be established to provide a framework for exchange and sharing of information.

Referencing against best practices and standards shall be established and reviewed regularly.

Partnerships, coordination & cooperation with all relevant stakeholders shall be strengthened.

5.2.4 A VIABLE AND RESPONSIBLE PHARMACEUTICAL INDUSTRY

The National Medicines Policy requires a continued existence of a responsible and viable pharmaceutical industry in Malaysia. It is essential that policies related to the industry and health be coordinated, providing a consistent and supportive environment for the industry through the provision of appropriate returns, incentives and support for research and development, innovations, manufacture, and supply of medicines.

Intellectual Property (IP) protection shall be in line with international standards, where the Malaysian Patent Laws are compliant with Trade Related aspects of Intellectual Property Rights (TRIPS) obligations. However, to address the public health needs, flexibilities under the TRIPS Agreement shall be used and the Doha Declaration on the TRIPS Agreement and Public Health shall be implemented.

A viable domestic pharmaceutical manufacturing industry can be forged through supportive and consistent national health, industrial and trade policies together with responsible private sector's inputs. The regulatory authority and stakeholders in industry are cognisant of the need for the industry to operate in a global environment through harmonisation of pharmaceutical manufacturing standard. Thus, all parties shall be committed to the promotion of a strong export culture consistent with standards and ethics endorsed by the World Health Organization.

Suitable support and incentives shall be in place to reward investments, research and development, innovations, and strong exports as well as to further incentivise local and foreign direct investments.

5.2.4.1 Domestic Pharmaceutical Manufacturing

The domestic pharmaceutical manufacturing industry shall provide Malaysian consumers with timely access to many cost-effective medicines in the Malaysian formulary. Domestic production of medicines to support local needs and the market shall therefore be encouraged.

Domestic manufacturers may be eligible for incentives subject to fulfilment of criteria established by the government. Export of locally produced medicines shall be encouraged to stimulate the expansion of the domestic pharmaceutical industry.

GLOSSARY

GLOSSARY

Best Practice Environment ~ Set of defined methods, processes, systems or practices used by a company or organization to meet performance and efficiency standards within their industry or organization. Best practices are guidelines which are used to obtain the most efficient and effective way of completing a task using repeatable and proven procedures.

Clinical Practice Guideline ~ Systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances. *(Committee to Advise the Public Health Service on Clinical Practice Guidelines, Institute of Medicine. Clinical practice guidelines: directions for a new program. Washington: National Academy Press; 1990. p. 38)*

Counterfeit Medicine ~ One which is deliberately and fraudulently labelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging. *(Dept. Essential Drugs and Other Medicines, WHO 1999)*

Dispensed Medicine ~ A medicine supplied by a registered medical practitioner, registered dentist or veterinary surgeon under and in accordance with Section 19 or supplied, for the purpose of the medical, dental or animal treatment, of a particular individual by a licensed pharmacist on the premises specified in his license. *(Poisons Act 1952)*

Efficacious ~ Scientifically shown to be effective in the prevention, alteration, management and/or cure of an illness. The evidence for efficacy will ideally be established from controlled clinical trials. In some cases, traditional or complementary medicine where only low level claims for efficacy are to be made [e.g., relief of minor symptoms] requirement for evidence of efficacy may be less stringent although quality and safety must be established.

Essential Medicines ~ Medicines that are required to treat the majority of conditions that are prevalent in a country in a cost-effective and efficient manner. The concept does not imply that no other medicines are useful, but these are most basic, indispensable and necessary for the healthcare of the majority of the population. They should be available at all times, in adequate amount and in the proper dosage forms, to all segments of the society. *(WHO 1975)*

Generic Medicine ~ A generic medicine is a pharmaceutical product, usually intended to be interchangeable with the innovator product, which is usually manufactured without a license from the innovator company and marketed after the expiry of patented or other exclusivity rights. *(WHO 1997, Comparative Analysis of National Drug Policies, Geneva, WHO/DAP/97.6)*

Good Distribution Practice ~ The part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegal imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products. *(WHO Technical Report Series, No. 957, 2010)*

Halal medicines ~ Medicines permitted by Islamic Law to be consumed by Muslims.

Healthcare Industry ~ The complex of preventive, remedial, and therapeutic services provided by hospitals and other institutions, nurses, doctors, dentists, medical administrators, government agencies, voluntary agencies, non-institutional care facilities, pharmaceutic and medical equipment manufacturers, and health insurance companies. *(Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier)*

Healthcare Provider ~ Any individual, institution, or agency that provides health services to healthcare consumers. *(Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier)*

International Nonproprietary Names ~ Identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name. *(Guidelines on the Use of International Non-Proprietary Names (INN) For Pharmaceutical Substance, WHO/PHARM S/NOM 1570)*

Licensed Pharmacist ~ A registered pharmacist who is the holder of a Type A License issued to him under Section 26 Poisons Act, 1952. *(Poisons Act, 1952)*

Life-saving Medicines ~ Medicines that require immediate administration within minutes post or during a medical emergency. Medicines which have the potential to sustain life and/or prevent further complications. *(essentialdrugs.org)*

Medicines ~ Refers to medications that are registered pharmaceutical drugs and traditional medicines.

Medicinal Product ~ Any substance or a combination of substances which may be presented as having properties for treating or preventing disease or used or administered either with a view to maintain, restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic reaction or make a medical diagnosis. *(Pharmacy Bill 2012 Draft)*

National Essential Medicines List ~ The National Essential Medicines List (NEML) is a regularly updated essential medicines list formulated by the Ministry of Health Malaysia after consultation with all stakeholders in the healthcare industry, for the use in both public and private sectors as one of the strategies to ensure that essential medicines are affordable to the public. The NEML shall serve as a guide for public sector medicines procurement, distribution and utilization; undergraduate, postgraduate and in-service training for health professionals and public education on quality medicines use; drug information to healthcare providers; support to the domestic pharmaceutical industry; medicine financing/ reimbursement schemes; and medicine donations. *(Pharmaceutical Services Division, Ministry of Health Malaysia)*

National Medicines Formulary ~ A comprehensive list of medicines that encompass the National Essential Medicines List approved by The National Drug and Therapeutic Committee. *(Pharmaceutical Services Division, Ministry of Health Malaysia)*

Orphan Medicine ~ Defined as a medicine, vaccine or in vivo diagnostic agent that is intended to treat, prevent or diagnose a rare disease or not commercially viable to supply to treat, prevent or diagnose another disease or condition. *(Therapeutic Goods Administration, Department of Health and Ageing, Australian Government)*

Payers ~ In health care, generally refers to entities other than the patient that finance or reimburse the cost of health services. In most cases, this term refers to insurance carriers, other third-party payers, or health plan sponsors (employers or unions). *(Mosby's Dental Dictionary, 2nd edition. © 2008 Elsevier, Inc.)*

Pharmaceutical Industry ~ Companies engaged in researching, developing, manufacturing, and marketing drugs and biological for human or veterinary use. *(International Trade Administration, Pharmaceutical Industry Profile 2010)*

Pharmaceutical product ~ Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage form or as a starting material for use in such a dosage form that is subject to control by pharmaceutical legislation in both the exporting state and the importing state. *(Good Practices for National Pharmaceutical Control Laboratories. Annex 3. WHO Technical Report Series. No.902.2002)*

Quality Assurance ~ A wide-ranging concept covering all matters that individually or collectively influences the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. *(Quality Assurance of Pharmaceuticals. A Compendium of guidelines and related materials Vol.2: Good manufacturing practices and inspection. Geneva, WHO 1999)*

Quality Control ~ Quality control covers all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics. *(Quality Assurance of Pharmaceuticals. A Compendium of guidelines and related materials Vol.2: Good manufacturing practices and inspection. Geneva, WHO 1999)*

Registered Dentist ~ A dental practitioner registered in Division I or Division II of the Register kept under Section 11 (1) of the Dental Act 1971; and "registered dentist Division I" and "registered dentist Division II" means a dental practitioner whose name has been registered in the first or second division respectively of the said Register. *(Poisons Act 1952)*

Registered Medical Practitioner ~ A medical practitioner registered under the Medical Act 1971. *(Dangerous Drug Act 1952)*

Registered Pharmacist ~ A person whose name appears for the time being in the Register kept under Registration of Pharmacists Act 1951. *(Registration of Pharmacists Act 1951)*

Stakeholder ~ A person or company that is involved in a particular organization, project, system, etc., especially because they have invested money in it. *(Oxford Advanced Learner's Dictionary)*

Traditional medicine ~ Any product used in the practice of indigenous medicine, in which the drug consist of solely one or more naturally occurring substance of a plant, animal or mineral, or parts thereof, in the unextracted or crude extract form, and a homeopathic medicine. *(Control of Drugs and Cosmetics Regulations 1984)*

ABBREVIATIONS

CPG	Clinical Practice Guidelines
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
ICT	Information and Communication Technology
INN	International Nonproprietary Names
NEML	National Essential Medicines List
STG	Standard Treatment Guidelines
TRIPS	Trade Related Intellectual Property Rights

Kementerian Kesihatan
Malaysia

DASAR UBAT NASIONAL (DUNas)

Edisi Kedua, 2012

ISI KANDUNGAN

ISI KANDUNGAN

PENGHARGAAN

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Pihak BPF juga ingin merakamkan penghargaan di atas sokongan dan sumbangan yang diberi dalam penyediaan dasar ini kepada para peserta dan pihak-pihak berkepentingan berikut:

- Bahagian Perkhidmatan Farmasi, Jabatan Kesihatan Negeri
- Biro Pengawalan Farmaseutikal Kebangsaan
- Bahagian Amalan Perubatan, Kementerian Kesihatan
- Bahagian Perkembangan Perubatan, Kementerian Kesihatan
- Bahagian Perancangan dan Pembangunan, Kementerian Kesihatan
- Bahagian Kewangan, Kementerian Kesihatan
- Bahagian Kesihatan Pergigian, Kementerian Kesihatan
- Bahagian Perolehan dan Penswastaan, Kementerian Kesihatan
- Bahagian Pembangunan Kesihatan Keluarga, Kementerian Kesihatan
- Bahagian Perubatan Tradisional dan Komplementari, Kementerian Kesihatan
- Bahagian Pendidikan Kesihatan, Kementerian Kesihatan
- Pusat Penyelidikan Klinikal, Kementerian Kesihatan
- Bahagian Dasar dan Hubungan Antarabangsa, Kementerian Kesihatan
- Bahagian Sumber Manusia, Kementerian Kesihatan
- Institut Pengurusan Kesihatan, Kementerian Kesihatan
- Institut Penyelidikan Sistem Kesihatan, Kementerian Kesihatan
- Bahagian Perkhidmatan Kesihatan Angkatan Tentera Malaysia, Kementerian Pertahanan
- Bahagian Perancangan Polisi/Dasar Pendidikan dan Kajian, Kementerian Pelajaran
- Kementerian Perdagangan dan Industri Antarabangsa
- Kementerian Sains, Teknologi dan Inovasi
- Unit Pengurusan Prestasi dan Perlaksanaan, Jabatan Perdana Menteri (PEMANDU)
- Universiti Malaya (UM)
- Universiti Sains Malaysia (USM)
- Universiti Kebangsaan Malaysia (UKM)

- Universiti Islam Antarabangsa Malaysia (UIAM)
- Universiti Teknologi MARA (UiTM)
- *International Medical University (IMU)*
- *University of Nottingham Malaysia Campus*
- Majlis Dekan Farmasi
- Pusat Perubatan Universiti Malaya
- Pusat Perubatan UKM
- Persatuan Perubatan Malaysia
- Persatuan Farmasi Malaysia (MPS)
- Akademi Farmasi Malaysia
- Organisasi Industri Farmaseutikal Malaysia (MOPI)
- Persatuan Farmaseutikal Malaysia (PhAMA)
- Persatuan Pembekal Farmaseutikal Malaysia (MAPS)
- Persatuan Hospital Swasta Malaysia (APHM)
- Persatuan Konsumer Pulau Pinang
- Persekutuan Persatuan Pengguna Malaysia (FOMCA)
- Lembaga Pembangunan Pelaburan Malaysia (MIDA)
- Pesuruhjaya Persaingan Malaysia (MyCC)
- Perbadanan Hak Intelek Malaysia (MyIPO)
- Institut Penyelidikan Perhutanan Malaysia (FRIM)
- Perbadanan Bioteknologi Malaysia Sdn. Bhd.
- Persatuan Insuran Am Malaysia (PIAM)
- Persatuan Jualan Langsung Malaysia (DSAM)
- Ahli Farmasi dan Penyedia Perubatan Hospital Kerajaan dan Swasta

DASAR UBAT NASIONAL (DUNas)

DASAR UBAT NASIONAL (DUNas)

PENDAHULUAN

Dasar Ubat Nasional (DUNas), yang telah diluluskan oleh Jemaah Menteri Malaysia pada bulan Oktober 2006, merupakan hala tuju negara untuk memastikan pengurusan ubat-ubatan baik demi mencapai hasil kesihatan *(health outcomes)* yang lebih baik untuk semua rakyat Malaysia. Semakan separuh penggal dasar ini telah dilakukan pada bulan Julai 2009 dan diikuti dengan semakan penuh pada bulan Oktober 2012.

Edisi kedua DUNas ini adalah hasil dari semakan dasar selepas lima tahun pelaksanaannya. Penilaian dan semakan semula dasar asal adalah perlu untuk mengambil kira isu-isu penting dan mengenal pasti penambahbaikan yang diperlukan bagi memenuhi keperluan penjagaan kesihatan semasa dan masa depan negara.

PENGENALAN

Objektif Dasar Ubat Nasional dikekalkan iaitu untuk menggalakkan keperolehan yang sama rata dan penggunaan yang rasional ubat-ubatan penting yang berkualiti, selamat, berkesan dan mampu dimiliki bagi meningkatkan tahap kesihatan rakyat.

Dalam tempoh lima tahun pelaksanaan dasar, ia telah menunjukkan hasil dan transformasi positif seperti mewujudkan satu sistem regulatori yang komprehensif, pengukuhan undang-undang dan peraturan-peraturan, mewujudkan industri farmaseutikal yang mantap serta membangunkan rangkaian pengedaran farmaseutikal yang menyeluruh. Walau bagaimanapun, masih terdapat ruang untuk penambahbaikan dan pengukuhan yang berterusan termasuk perlu mengambil kira idea-idea baru.

Kenyataan dasar dan strategi baru yang diperkenalkan adalah penting untuk memastikan sektor farmaseutikal dan kesihatan maju ke hadapan di samping menyediakan keperluan semasa negara serta memperbaiki dan menyokong dasar-dasar kerajaan yang sedia ada selaras dengan perkembangan global semasa.

Empat komponen teras dan empat komponen sokongan dasar asal telah disusun semula. Komponen *Kualiti, Keselamatan dan Keberkesanan* serta *Penggunaan Ubat-ubatan Secara Berkualiti* dikekalkan. Komponen *Ketersediaan Ubat-ubatan* dan *Kemampuan Mendapat Ubat-ubatan* telah digabungkan menjadi satu komponen yang dinamakan *Keperolehan Ubat-ubatan* supaya tiada pertindihan strategi dan isu. *Komponen Pembangunan Sumber Manusia, Kerjasama Penyelidikan* dan *Pembangunan dan Kerjasama Teknikal* telah digabungkan sebagai satu komponen yang dinamakan sebagai *Perkongsian dan Kerjasama dalam Industri Penjagaan Kesihatan*. Satu komponen baharu mengenai tadbir urus dalam ubat-ubatan telah diperkenalkan dalam dasar yang telah disemak.

Modifikasi ini telah menghasilkan lima komponen berikut:

i. Tadbir Urus Dalam Ubat-ubatan
ii. Kualiti, Keselamatan dan Keberkesanan Ubat-ubatan
iii. Keperolehan Ubat-ubatan
iv. Penggunaan Ubat-ubatan Secara Berkualiti
v. Perkongsian dan Kerjasama untuk Industri Penjagaan Kesihatan

1
TADBIR URUS DALAM UBAT-UBATAN

1. TADBIR URUS DALAM UBAT-UBATAN

POLISI

Tadbir urus baik, amalan, kod etika dan profesionalisme akan ditekankan dalam industri penjagaan kesihatan ke arah mencapai hasil kesihatan *(health outcomes)* yang optimum.

1.1 MATLAMAT

Untuk mempunyai tadbir urus yang sesuai bagi memastikan penyediaan ubat-ubatan yang selamat, berkesan dan mampu dimiliki dalam persekitaran amalan terbaik.

Untuk memastikan semua pihak yang berkepentingan bertanggungjawab dalam perilaku yang beretika dan profesional.

Untuk memastikan peraturan-peraturan dapat memudahcara dan menyokong penyediaan ubat-ubatan yang selamat, berkesan dan mampu dimiliki.

1.2 STRATEGI

Badan-badan profesion kesihatan dan pihak berkepentingan perlu mempunyai kod etika dan bertanggungjawab dalam memastikan pematuhan kod tersebut oleh ahli-ahlinya.

Pihak yang berkepentingan hendaklah bertindak mengikut piawaian amalan yang dibangunkan oleh pihak berkuasa atau badan-badan profesional yang berkenaan. Pematuhan kepada piawaian hendaklah disokong oleh undang-undang yang sesuai.

Undang-undang dan peraturan yang berkenaan hendaklah dibangunkan dan dikaji semula secara berkala untuk memastikan rangkaian bekalan yang cekap dan pengurusan ubat-ubatan secara bersepadu untuk melindungi orang awam.

2

KUALITI, KESELAMATAN DAN KEBERKESANAN UBAT-UBATAN

2. KUALITI, KESELAMATAN DAN KEBERKESANAN UBAT-UBATAN

POLISI

Hanya ubat-ubatan yang selamat, berkesan dan berkualiti yang memenuhi piawaian dan spesifikasi sahaja boleh didaftarkan dan diperolehi untuk jualan dan digunakan di Malaysia.

2.1 MATLAMAT

Untuk memastikan ubat-ubatan yang dipasarkan untuk pengguna adalah selamat, berkesan dan berkualiti serta untuk menggalakkan penggunaan ubat-ubatan secara berkualiti untuk memenuhi keperluan kesihatan negara.

2.2 STRATEGI

Matlamat akan dicapai dengan memperkukuhkan sistem regulatori ubat-ubatan melalui satu rangka kerja perundangan ubat-ubatan yang komprehensif, meningkatkan langkah-langkah kepastian kualiti farmaseutikal dan pemantauan pasca-pemasaran yang berkesan melalui kerjasama dan kolaborasi antara pihak berkuasa dan pihak-pihak berkepentingan.

2.2.1 UNDANG-UNDANG DAN PERATURAN

Undang-undang yang berkesan dan komprehensif mengenai ubat-ubatan hendaklah diuruskan untuk memastikan Dasar Ubat Nasional dilaksanakan. Undang-undang dan peraturan-peraturan mengenai ubat hendaklah diuruskan melalui kriteria dan proses yang telus dan adil.

Peraturan-peraturan perlu diperkukuhkan untuk memastikan amalan yang betul dipatuhi dalam pembangunan, pengeluaran, pengimportan, pembekalan, pemasaran, penjualan dan pengurusan (termasuk *prescribing*, pendispensan, pemberian dan pelupusan) ubat-ubatan.

Tahap peraturan hendaklah konsisten dengan manfaat dan risiko yang dihadapi oleh masyarakat.

2.2.1.1 Biro Pengawalan Farmaseutikal Kebangsaan (BPFK)

Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) hendaklah bertanggungjawab ke atas kawalan regulatori farmaseutikal di Malaysia dari segi:

- Pelesenan untuk pengilang, pengimport dan pemborong
- Pendaftaran ubat-ubatan
- Kawalan kualiti ubat-ubatan
- Pematuhan Amalan Makmal Baik
- Aktiviti pemantauan pasca pemasaran
- Kawalan ubat-ubatan yang digunakan dalam ujian klinikal

BPFK hendaklah bekerjasama dengan industri dan pihak berkepentingan lain untuk memperkukuhkan rangka kerja regulatori dan penglibatan masyarakat, meningkatkan komunikasi dan menggalakkan penggunaan ubat-ubatan secara berkesan oleh pengguna.

BPFK hendaklah memainkan peranan penting dalam memudahcara pengharmonian keperluan teknikal bagi pendaftaran ubat-ubatan di peringkat serantau dan antarabangsa.

2.2.1.2 Pengawalan Premis yang Membekalkan Ubat

Hanya pengilang, pengimport dan pemborong berlesen sahaja yang boleh mengendalikan ubat-ubatan yang berdaftar.

Penjualan, pembekalan dan pendispensan ubat-ubatan hendaklah dijalankan di premis yang dikawal selia mengikut undang-undang yang tertentu.

2.2.1.3 Penguatkuasaan Berkesan

Undang-undang dan peraturan-peraturan ubat-ubatan hendaklah disokong oleh penguatkuasaan yang mencukupi dan berkesan untuk memastikan semua aktiviti dalam sektor pengilangan dan pembekalan ubat-ubatan mematuhi undang-undang, peraturan-peraturan, garis panduan dan arahan yang sedia ada.

Premis yang mengilang, mengimport, membekal atau mendispen ubat-ubatan hendaklah diperiksa secara berkala untuk memastikan pematuhan kepada keperluan undang-undang yang sedia ada.

2.2.1.4 Pengiklanan dan Promosi Ubat-ubatan

Semua pihak yang berkepentingan hendaklah mematuhi undang-undang, garis panduan dan kod etika yang sedia ada untuk pengiklanan dan promosi.

2.2.1.5 Ubat Palsu

Undang-undang dan rangka kerja teknikal yang sesuai untuk usaha bersepadu dalam penguatkuasaan undang-undang dan peraturan-peraturan oleh Kementerian Kesihatan dan pihak berkuasa lain yang berkaitan dengan pemantauan pasaran, hendaklah terus dipertingkatkan untuk mengatasi masalah ubat-ubatan palsu.

Langkah keselamatan yang sesuai untuk menentukan ketulenan, pengesanan ubat palsu dan pendidikan awam hendaklah dilaksanakan dan dipertingkatkan secara berterusan.

2.2.2 KEPASTIAN KUALITI FARMASEUTIKAL

2.2.2.1 Pemantauan Pasca Pemasaran

Pemantauan berterusan ke atas produk-produk yang terdapat di pasaran hendaklah dilaksanakan untuk memastikan pematuhan produk-produk tersebut kepada piawaian dan keperluan semasa. Tindakan punitif hendaklah diambil ke atas produk yang tidak patuh.

2.2.2.2 Pengurusan Aduan tentang Ubat-ubatan

Semua aduan yang berkaitan dengan ubat-ubatan hendaklah disiasat dan tindakan yang sewajarnya hendaklah diambil.

3
KEPEROLEHAN UBAT-UBATAN

3. KEPEROLEHAN UBAT-UBATAN

POLISI

Pengurusan dan rangkaian pembekalan ubat-ubatan yang cekap dan bersepadu hendaklah dikekalkan. Industri farmaseutikal hendaklah diselenggara dan dikawal selia untuk menghasilkan insentif dan menggalakkan persaingan bagi harga ubat-ubatan. Mekanisme pembiayaan yang bersesuaian hendaklah dibangunkan untuk memastikan ubat-ubatan penting yang diperlukan untuk penjagaan kesihatan yang berkualiti adalah mampu dimiliki.

3.1 MATLAMAT

Untuk memastikan keperolehan ubat-ubatan yang berkualiti, selamat dan mampu dimiliki adalah mencukupi, berterusan dan sama rata supaya mencapai hasil kesihatan *(health outcomes)* yang optimum.

3.2 STRATEGI

Matlamat hendaklah dicapai dengan memastikan ketersediaan dan kemampuan mendapat ubat-ubatan melalui:

- Satu mekanisme pemilihan ubat-ubatan yang adil dan telus selaras dengan keperluan kesihatan negara yang menekankan keberkesanan klinikal dan keberkesanan kos rawatan
- Satu mekanisme perolehan yang cekap dan berkesan dan rangkaian pembekalan ubat-ubatan yang berkualiti
- Satu mekanisme pembiayaan pengurusan yang cekap untuk mencapai tahap kesihatan yang optimum bagi memastikan pulangan yang berpadanan dengan harga.

3.2.1 KETERSEDIAAN UBAT-UBATAN

Ketersediaan ubat-ubatan hendaklah dicapai melalui pemilihan ubat-ubatan secara wajar, penambahbaikan pengurusan perolehan ubat-ubatan dan rangkaian pembekalan ubat, serta melalui penggunaan sumber-sumber kewangan secara optimum bagi memastikan kemampanan.

3.2.1.1 Pemilihan Ubat-ubatan

Pemilihan ubat adalah telus dan berdasarkan prinsip-prinsip kualiti, keselamatan, keberkesanan klinikal dan kos rawatan berdasarkan Garis Panduan Amalan Klinikal (CPG).

3.2.1.1.1 Formulari Ubat Kebangsaan

Formulari Ubat Kebangsaan yang merangkumi Senarai Ubat-ubatan Penting Kebangsaan hendaklah dibangunkan oleh Jawatankuasa Ubat-ubatan dan Terapeutik Kebangsaan sebagai rujukan standard untuk negara.

Formulari Ubat Kebangsaan merupakan satu panduan untuk *prescribing* dan seterusnya menyediakan maklumat yang praktikal dan autoritatif kepada profesional penjagaan kesihatan mengenai pemilihan dan penggunaan klinikal ubat-ubatan secara jelas, tepat dan boleh dicapai.

3.2.1.1.2 Senarai Ubat-ubat Penting Kebangsaan (NEML)

NEML hendaklah disemak semula dan dikemas kini secara berkala dan merupakan rujukan kebangsaan kepada industri ubat-ubatan tempatan bagi tujuan pengilangan, perolehan, pengagihan, penggunaan dan penyelidikan serta kurikulum pengajaran ahli akademik dalam bidang penjagaan kesihatan.

3.2.1.1.3 Jawatankuasa Ubat-ubatan dan Terapeutik

Jawatankuasa Ubat-ubatan dan Terapeutik Kebangsaan di bawah naungan Kementerian Kesihatan hendaklah diwakili oleh semua pihak berkepentingan.

Jawatankuasa Ubat-ubatan dan Terapeutik di institusi dan fasiliti kesihatan hendaklah bertanggungjawab dalam pemilihan ubat-ubatan, memastikan ketersediaan dan kemampuan mendapatkan ubat oleh penyedia penjagaan kesihatan mereka. Jawatankuasa hendaklah membangunkan dan menyelaraskan polisi dalaman berkaitan ubat-ubatan dengan merujuk kepada Formulari Ubat Kebangsaan dan amalan klinikal standard.

Jawatankuasa Ubat-ubatan dan Terapeutik boleh mencadangkan dan memutuskan penggunaan ubat-ubatan yang tidak tersenarai dalam Formulari Ubat Kebangsaan bergantung kepada keperluan klinikal dan peruntukan sumber. Walau bagaimanapun, Jawatankuasa Ubat-ubatan dan Terapeutik Kebangsaan hendaklah memantau penggunaan ubat-ubatan tersebut.

Semua Jawatankuasa Ubat-ubatan dan Terapeutik hendaklah ditubuhkan mengikut garis panduan Kementerian Kesihatan.

3.2.1.1.4 Formulari Ubat Tradisional dan Komplementari

Formulari Ubat Tradisional dan Komplementari hendaklah dibangunkan oleh jawatankuasa penasihat pakar di bawah naungan Kementerian Kesihatan. Formulari ini hendaklah bertindak sebagai panduan penggunaan ubat-ubatan tradisional dan komplementari berdaftar oleh penyedia penjagaan kesihatan.

3.2.1.1.5 Ubat Penyelamat Nyawa dan Ubat *Orphan*

Prosedur yang sesuai hendaklah diwujudkan untuk meningkatkan keperolehan ubat penyelamat nyawa dan ubat orphan tanpa menjejaskan keselamatan, kualiti dan keberkesanan.

3.2.1.1.6 Ubat-ubatan Halal

Kerjasama strategik dengan pihak berkuasa yang berkaitan hendaklah diwujudkan untuk memastikan ketersediaan ubat-ubatan halal di Malaysia.

3.2.1.2 Pembekalan Ubat-ubatan

Pembekalan ubat-ubatan yang selamat, berkesan dan berkualiti hendaklah sama rata, mencukupi dan tepat pada masanya. Ini hendaklah dicapai melalui pelaksanaan:

- Pengurusan yang berkesan rangkaian pembekalan ubat-ubatan berdasarkan sistem kualiti yang menyeluruh
- Rangkaian pembekalan ubat-ubatan yang cekap berdasarkan Amalan Pengedaran Baik (GDP)
- Teknologi Maklumat dan Komunikasi yang berkesan dan bersepadu (ICT) untuk menyokong rangkaian pembekalan ubat-ubatan

3.2.1.2.1 Perolehan

Satu sistem perolehan yang cekap, berkesan dan telus hendaklah diperkukuhkan untuk memastikan ketersediaan ubat-ubatan yang mencukupi dan tepat pada masanya.

3.2.1.2.2 Pengagihan dan Penyimpanan Ubat-ubatan

Rangkaian pengagihan yang berkesan dan ekonomi hendaklah diperkukuhkan untuk memastikan pengagihan ubat-ubatan berkualiti yang mencukupi kepada pengguna.
Penyimpanan, kawalan inventori dan kepastian kualiti di fasiliti dan di seluruh rangkaian pembekalan ubat hendaklah mematuhi keperluan GDP untuk memastikan kualiti dan keselamatan ubat-ubatan.

Rangkaian ICT untuk logistik, inventori dan transaksi kewangan hendaklah diwujudkan dan diintegrasikan di semua fasiliti penjagaan kesihatan.

3.2.1.2.3 Pelupusan Ubat-ubatan

Pelupusan ubat-ubatan hendaklah dilakukan mengikut peraturan-peraturan dan garis panduan yang sedia ada.

3.2.1.2.4 Bekalan Ubat dalam Situasi Kecemasan dan Pendermaan Ubat-ubatan

Semua organisasi akan bekerjasama untuk menguruskan situasi kecemasan kebangsaan bagi memastikan pembekalan ubat-ubatan ini tepat pada masanya tanpa menjejaskan keselamatan, kualiti dan keberkesanan.

Pengurusan ubat-ubatan dalam situasi kecemasan atau pendermaan hendaklah berdasarkan keperluan yang disarankan oleh Garis Panduan WHO.

3.2.2 KEMAMPUAN MENDAPAT UBAT-UBATAN

Ubat-ubatan yang diperlukan untuk penjagaan kesihatan yang berkualiti hendaklah mampu dimiliki oleh semua. Kos tidak sepatutnya menjadi penghalang dalam memastikan ketersediaan ubat-ubatan. Usaha hendaklah diambil untuk menggalakkan persaingan yang sihat ke arah rawatan yang sama rata, telus dan kos efektif serta mampu bertahan.

3.2.2.1 Rujukan Harga Ubat Kebangsaan (National Pricing Reference for Medicines)

Rujukan Harga Ubat Kebangsaan untuk Formulari Ubat Kebangsaan hendaklah dibangunkan oleh jawatankuasa yang terdiri daripada pihak-pihak berkepentingan. Ia hendaklah merangkumi prinsip-prinsip kesamarataan, kemampuan dan ketelusan.

3.2.2.1.1 Ketelusan Maklumat Harga

Semua pihak yang berkepentingan hendaklah berusaha bersama untuk mencapai ketelusan harga ubat di Malaysia melalui:

- Pembangunan pangkalan data harga ubat-ubatan
- Ketersediaan Harga Runcit Disyorkan *(Recommended Retail Price - RRP)* untuk keperolehan awam
- Bil terperinci yang wajib menunjukkan harga bagi setiap item yang dibeli atau dibekalkan di semua saluran pendispensan
- Ketersediaan data tentang maklumat paten

3.2.2.1.2 Pemantauan Maklumat Harga

Harga tempatan dan antarabangsa ubat-ubatan hendaklah dipantau secara berkala untuk mengesan perubahan harga dan faktor-faktor yang mempengaruhinya dalam pasaran supaya tindakan boleh diambil untuk mengawal sebarang kenaikan harga.

3.2.2.1.3 Tarif dan Cukai

Bekalan ubat-ubatan hendaklah terus diberi pengecualian daripada tarif dan cukai.

3.2.2.2 Pembiayaan Ubat

Mekanisme pembiayaan ubat yang wajar, mampu dimiliki dan mampan hendaklah dibangunkan untuk mencapai keperolehan ubat-ubatan secara universal. Perancangan, pembelanjawanan dan pembiayaan yang mencukupi untuk bekalan ubat-ubatan hendaklah dilaksanakan dengan penekanan kepada langkah-langkah untuk mengawal kos.

Mekanisme pembiayaan hendaklah memastikan golongan miskin dan kurang bernasib baik tidak dinafikan keperolehan ubat-ubatan penting.

3.2.2.3 Dasar Ubat Generik

Dasar Ubat Generik hendaklah dilaksanakan untuk merangsang persaingan yang sihat dalam harga ubat-ubatan. Dasar ini hendaklah digunakan sebagai panduan dalam penggunaan dan perolehan ubat-ubatan seperti berikut:

- *Prescribing* dengan menggunakan nama generik *(International Non-proprietary Name – INN)* hendaklah diamalkan
- Perolehan ubat-ubatan melalui nama generik hendaklah digalakkan
- Dalam pemilihan yang dilakukan untuk perolehan, keutamaan hendaklah diberikan kepada ubat-ubatan keluaran tempatan
- Semua ubat-ubatan yang didispens hendaklah dilabelkan dengan lebih jelas menggunakan nama generik dengan/atau tanpa nama jenama
- Satu senarai ubat-ubatan yang boleh saling bertukar ganti dan tidak boleh saling bertukar ganti hendaklah disediakan
- Penggantian ubat generik hendaklah dibenarkan dan sah dari segi perundangan bagi semua ubat yang boleh saling bertukar ganti
- Insentif yang sesuai untuk menggalakkan penggunaan dan pengeluaran ubat-ubatan generik tempatan hendaklah diperkenalkan

4

PENGGUNAAN UBAT-UBATAN SECARA BERKUALITI

4. PENGGUNAAN UBAT-UBATAN SECARA BERKUALITI

POLISI

Penggunaan ubat-ubatan secara berkualiti adalah tanggungjawab semua pihak yang berkepentingan. Aktiviti oleh pihak-pihak berkepentingan untuk menyokong penggunaan ubat-ubatan yang bersesuaian dan berdasarkan maklumat hendaklah digalakkan.

4.1 MATLAMAT

Untuk memastikan ubat-ubatan digunakan secara bijak, sesuai, selamat dan kos efektif ke arah menggalakkan hasil kesihatan *(health outcomes)* yang lebih baik.

4.2 STRATEGI

Matlamat hendaklah dicapai melalui:

- Pembangunan dan pelaksanaan model amalan terbaik *(best practice)*
- Pendidikan dan latihan
- Penyediaan maklumat ubat-ubatan yang betul dan tepat pada masanya
- Pengukuhan penjagaan kesihatan berterusan *(seamless care)* antara penyedia penjagaan kesihatan awam dan swasta
- Penyelidikan dan pembangunan dalam penggunaan ubat-ubatan secara berkualiti
- Keterlibatan pembayar dalam pembayaran balik *(reimbursement)* untuk penggunaan ubat

4.2.1 PEMBANGUNAN DAN PELAKSANAAN MODEL AMALAN TERBAIK *(BEST PRACTICE)*

Standard amalan terbaik *(best practice)* hendaklah diaplikasi dan dipantau untuk memastikan penggunaan ubat-ubatan secara selamat dan berkualiti di semua peringkat penjagaan kesihatan.

Prescribing dan pendispensan ubat-ubatan hendaklah selaras dengan Garis Panduan Amalan Klinikal (CPG), Garis Panduan Terapi Standard *(Standard Treatment Guidelines - STG)*, Amalan Pendispensan Baik *(Good Dispensing Practice)* dan garis panduan lain yang berkaitan dengan mengambil kira prinsip-prinsip kualiti, keselamatan dan keberkesanan kos. Garis panduan ini hendaklah disediakan dan mudah dicapai oleh semua penyedia penjagaan kesihatan dan pihak berkepentingan. Semakan dan pengemaskinian garis panduan secara berkala hendaklah dilakukan sejajar dengan amalan antarabangsa dan keperluan tempatan.

Aktiviti audit dan pemantauan secara berkala hendaklah dilaksanakan untuk memastikan pematuhan kepada garis panduan yang berkaitan.

Mekanisme yang sedia ada untuk pembangunan dan pengemaskinian dokumen panduan, garis panduan klinikal, penilaian teknologi kesihatan dan penilaian farmakoekonomik untuk negara hendaklah diperkukuhkan.

4.2.2 PENDIDIKAN DAN LATIHAN

4.2.2.1 Penyedia Penjagaan Kesihatan

Kurikulum bagi pendidikan dan latihan untuk semua penyedia penjagaan kesihatan yang terlibat dalam pengurusan ubat-ubatan hendaklah merangkumi prinsip-prinsip penggunaan ubat-ubatan secara selamat, sesuai dan berkualiti.

4.2.2.2 Pengguna

Celik kesihatan *(health literacy)* dan pemerkasaan pengguna untuk menguruskan ubat-ubatan mereka hendaklah dipertingkatkan.

Bidang yang ditumpukan termasuk:

- Pematuhan kepada ubat-ubatan
- Menggalakkan sikap yang lebih menilai *(discerning attitude)* terhadap sumber maklumat ubat-ubatan
- Menggalakkan pengambilan keputusan yang berasaskan pengetahuan ke atas pengubatan kendiri yang bertanggungjawab
- Penyimpanan ubat-ubatan secara betul dan pelupusan ubat-ubatan secara selamat
- Keyakinan untuk berinteraksi dengan penyedia penjagaan kesihatan

Pendidikan dan latihan pengguna adalah tanggungjawab bersama antara Kementerian Kesihatan dan pihak-pihak berkepentingan yang lain.

4.2.2.3 Industri Farmaseutikal

Semua kakitangan yang terlibat dalam penjualan dan promosi ubat-ubatan hendaklah mempunyai latihan yang mencukupi dalam penggunaan ubat-ubatan secara berkualiti dan dikawal oleh kod etika.

4.2.2.4 Media

Semua petugas media yang terlibat dalam melapor isu kesihatan hendaklah mempunyai latihan dan pendidikan yang sesuai mengenai penggunaan ubat-ubatan secara berkualiti.

4.2.3 PENYEDIAAN MAKLUMAT UBAT-UBATAN YANG BETUL DAN TEPAT PADA MASANYA

4.2.3.1 Penyedia Penjagaan Kesihatan

Maklumat yang tidak berat sebelah, berkualiti serta berasaskan bukti hendaklah disediakan untuk penyedia penjagaan kesihatan melalui program pendidikan berterusan, promosi ubat-ubatan yang tidak berat sebelah dan capaian kepada Pusat Maklumat Ubat Kebangsaan dan portal kesihatan lain yang berkaitan.

4.2.3.2 Pengguna

Pengguna hendaklah mempunyai akses kepada maklumat yang tepat mengenai ubat-ubatan daripada pelbagai sumber termasuk daripada penyedia penjagaan kesihatan dan portal kesihatan.

4.2.3.3 Industri Farmaseutikal

Industri farmaseutikal hendaklah menyediakan maklumat yang seimbang dan bertanggungjawab dalam mempromosikan ubat-ubatan kepada penyedia penjagaan kesihatan dan pengguna.

Mereka hendaklah memastikan pembungkusan, risalah maklumat produk dan pelabelan ubat adalah tepat, mencukupi dan tidak berat sebelah.

Pengiklanan dan promosi ubat-ubatan secara beretika akan memudahcara penggunaan ubat-ubatan secara berkualiti.

4.2.3.4 Media

Pihak media hendaklah melaporkan isu-isu tentang ubat-ubatan secara tepat dan bertanggungjawab.

Agensi-agensi yang berkaitan dan pihak yang berkepentingan hendaklah memberikan maklum balas yang tepat pada masanya dalam kes-kes salah maklumat *(misinformation)*.

4.2.4 PENGUKUHAN PENJAGAAN BERTERUSAN *(SEAMLESS CARE)* ANTARA PENYEDIA PENJAGAAN KESIHATAN AWAM DAN SWASTA

Teknologi Maklumat dan Komunikasi (ICT) yang menyeluruh hendaklah dibangunkan sebagai pemangkin penjagaan berterusan *(seamless care)*.

Keperolehan yang mencukupi kepada rekod perubatan pesakit, contohnya, sejarah pengubatan, alahan ubat, dan sebagainya, hendaklah disediakan untuk membantu kesinambungan penjagaan kesihatan tanpa menjejaskan kerahsiaan pesakit.

Perkongsian dan kerjasama pintar hendaklah dioptimakan untuk penjagaan terbaik bagi pesakit.

4.2.5 PENYELIDIKAN DAN PEMBANGUNAN DALAM PENGGUNAAN UBAT SECARA BERKUALITI

Kajian hendaklah dijalankan untuk menilai keberkesanan program penggunaan ubat-ubatan secara berkualiti dan untuk mengenal pasti bidang-bidang yang memerlukan penambahbaikan.

4.2.6 KETERLIBATAN PEMBAYAR DALAM PEMBAYARAN BALIK *(REIMBURSEMENT)* BAGI PENGGUNAAN UBAT

Pembayar hendaklah bertanggungjawab untuk menyokong dan melibatkan diri dalam aktiviti penggunaan ubat-ubatan secara berkualiti bagi tujuan mengoptimakan hasil kesihatan *(health outcomes)*.

5
PERKONGSIAN DAN KERJASAMA BAGI INDUSTRI KESIHATAN

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POLISI

Perkongsian dan kerjasama dalam pelaksanaan dan pengukuhan bidang yang berkaitan dalam industri penjagaan kesihatan hendaklah diwujudkan di kalangan pelbagai pihak yang berkepentingan di peringkat kebangsaan, serantau dan antarabangsa.

5.1 MATLAMAT

Untuk memastikan supaya perkongsian dan kerjasama antara semua pihak yang berkepentingan dalam industri penjagaan kesihatan mematuhi amalan terbaik dan piawaian yang berkaitan dengan ubat-ubatan di peringkat kebangsaan, serantau dan antarabangsa.

5.2 STRATEGI

Matlamat hendaklah dicapai melalui:

- Penglibatan awal dan berterusan semua pihak yang berkepentingan
- Memastikan kemampanan sumber manusia yang berkelayakan, cekap dan berkesan berdasarkan keperluan melalui:
  - Latihan dan pembangunan
  - Pembangunan dan kemajuan laluan kerjaya profesional
- Perkongsian maklumat, kepakaran, kemahiran dan kemudahan
- Membangunkan industri farmaseutikal tempatan yang berdaya maju dan bertanggungjawab

5.2.1 PEMBANGUNAN SUMBER MANUSIA

Mekanisme kepastian kualiti hendaklah dibangunkan, disemak semula dan dikuatkuasakan ke atas semua penyedia latihan supaya mematuhi polisi dan piawaian.

Transformasi penyedia latihan diperlukan untuk menghasilkan ahli penjagaan kesihatan profesional yang berkualiti dan dapat berfungsi dengan cekap serta berkesan demi memenuhi keperluan penjagaan kesihatan di negara ini.

Program latihan untuk penyedia penjagaan kesihatan dan pihak berkepentingan hendaklah diadakan yang merangkumi konsep yang berkaitan bagi memastikan penggunaan ubat-ubatan secara berkualiti.

Laluan kerjaya bagi penyedia penjagaan kesihatan hendaklah dikenal pasti dan dilaksanakan untuk pembangunan kerjaya di masa hadapan.

5.2.2 PENYELIDIKAN DAN PEMBANGUNAN

Penyelarasan di antara institusi penyelidikan dan kementerian berkaitan hendaklah diperkukuhkan.

Penyelidikan dalam bidang keutamaan hendaklah dikenal pasti dan disemak semula secara berkala untuk pelaksanaan.

Penyelidikan dan pembangunan yang inovatif hendaklah digalakkan melalui pemberian insentif yang sesuai.

Kerjasama antara syarikat-syarikat asing dan tempatan dalam pemindahan, pemerolehan dan pembangunan teknologi hendaklah digalakkan.

5.2.3 KERJASAMA DAN PERKONGSIAN TEKNIKAL

Kerjasama dan perkongsian teknikal hendaklah merangkumi semua bidang yang berkaitan dengan amalan regulatori, latihan dan pembangunan sumber manusia, keperolehan ubat-ubatan, penggunaan ubat secara berkualiti serta penyelidikan dan pembangunan.

Rangkaian yang efektif hendaklah diwujudkan bagi menyediakan satu rangka kerja untuk pertukaran dan perkongsian maklumat.

Rujukan mengenai amalan terbaik dan piawaian hendaklah diwujudkan dan disemak semula secara berkala.

Perkongsian, penyelarasan dan kerjasama dengan semua pihak yang berkaitan hendaklah diperkukuhkan.

5.2.4 INDUSTRI FARMASEUTIKAL YANG BERDAYA MAJU DAN BERTANGGUNGJAWAB

Dasar Ubat Nasional memerlukan kewujudan secara berterusan industri farmaseutikal yang bertanggungjawab dan berdaya maju di Malaysia. Polisi-polisi yang berkaitan dengan industri dan kesihatan hendaklah diselaraskan bagi menyediakan persekitaran yang konsisten dan menyokong industri melalui peruntukan pulangan yang sesuai, insentif dan sokongan untuk penyelidikan dan pembangunan, inovasi, pengeluaran dan bekalan ubat-ubatan.

Hak Intelek (IP) hendaklah diselaraskan dengan piawaian antarabangsa di mana Undang-undang Paten di Malaysia mematuhi obligasi *Trade Related aspects of Intellectual Property Rights (TRIPS)*. Walau bagaimanapun, untuk memenuhi keperluan kesihatan awam, fleksibiliti di bawah perjanjian TRIPS hendaklah digunakan dan *Doha Declaration on the TRIPS Agreement and Public Health* hendaklah dilaksanakan.

Industri farmaseutikal tempatan yang berdaya saing hendaklah dibangunkan melalui polisi kesihatan kebangsaan, industri dan perdagangan yang konsisten dan input sektor swasta yang berkaitan. Pihak berkuasa regulatori dan pihak berkepentingan dalam industri hendaklah menyedari keperluan bagi industri untuk beroperasi dalam persekitaran global melalui harmonisasi piawaian pengilangan farmaseutikal *(harmonisation of pharmaceutical manufacturing standard)*. Oleh itu, semua pihak hendaklah komited untuk mempromosikan budaya eksport yang kukuh dan konsisten dengan piawaian dan etika yang disahkan oleh Pertubuhan Kesihatan Sedunia (WHO).

Sokongan dan insentif yang sesuai hendaklah diwujudkan untuk memberi ganjaran bagi pelaburan, penyelidikan dan pembangunan, inovasi, dan eksport yang kukuh serta untuk menggalakkan pelaburan langsung tempatan dan asing *(local and foreign direct investment)*.

5.2.4.1 Pengilangan Farmaseutikal Tempatan

Industri pengilangan farmaseutikal tempatan hendaklah menyediakan untuk pengguna Malaysia keperolehan yang tepat pada masanya kepada banyak ubat-ubatan yang kos efektif dalam Formulari Malaysia. Pengilangan farmaseutikal tempatan untuk menampung keperluan tempatan dan pasaran hendaklah digalakkan.

Pengilang farmaseutikal tempatan mungkin layak untuk insentif tertakluk kepada kriteria yang ditetapkan oleh Kerajaan. Eksport ubat-ubatan keluaran tempatan hendaklah digalakkan untuk merangsang perkembangan industri farmaseutikal tempatan.

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